K063579

510(K) Summary of Safety and Effectiveness

As required by 807.92

DEC 14 2006

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Phil Chen
CHILIN TECHNOLOGY CO., LTD.
No.71, Te Lun Road, Jen Te Hsian, Tainan County 717, Taiwan, R.O.C.
Ph: +886-6-279 - 4113 ext. 533
Facsimile: +886-6-249 – 4751

2. DATE SUMMARY PREPARED

08 September 2006

3. DEVICE NAME

Trade Name: Medical Display, MDC2130-2HC
Common Name: Color LCD Monitor, Monochrome Diagnostic Display, etc.
Classification Name: System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. PREDICATE DEVICE

Medical Display - MDC1900-1LG 19" color LCD Monitor by CHILIN TECHNOLOGY CO., LTD. (K061305).

5. DEVICE DESCRIPTION

Medical Display, MDC2130-2HC is a 21.3" color LCD monitor that displays image for medical use. It provides 2 mega pixel (1600 x 1200) resolution and enable the user to define desired DICOM GSDF Gamma settings such as 1.8, 2.0 and 2.2 for more precise diagnose use in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

6. DEVICE OF INTEND USE

Medical Display, MDC2130-2HC is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system

7. CONCLUSION

Medical Display, MDC2130-2HC has the same intended use as the predicate device MDC1900-1LG, and they both share the similar characteristics except some minor differences which do not raise new questions of safety and effectiveness. The device does not contact with the patient nor does it control any life sustaining device. Therefore we concluded that it is substantially equivalent to MDC1900-1LG by CHILIN TECHNOLOGY CO., LTD. (K061305).

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K063579 Third Party Organization: Underwriters Inc
Third Party's Primary Reviewer(s): Thomas Huang
ODE/OIVD Division: ODE Branch/Team: DRARD/RADB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ____ Other (specify): ____
ODE/OIVD final decision: SE ✓ NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation			
d. Determination of 510(k) administrative completeness (screening review)			
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences			
g. Rationale for conclusions and recommendation		✓	
h. Use of guidance documents and standards			
i. Resolution of 510(k) deficiencies and FDA requests for additional information			
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues):

Section 4 – ODE/OIVD Assessor Information

Assessed by: Kam Date: 12-5-06 Tel No.: 276-3967

Routing: Division: Clip completed assessment (this page only) to inside front cover of 510(k).
DMC: Forward this page only to Eric Rechen, POS/ODE, Rm 120J, Corp Blvd (HFZ-402)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 14 2006

CHI LIN Technology Co., Ltd.
c/o Mr. Marc M. Mouser
Sr. Project Engineer, Program Reviewer
Underwriter Laboratories, Inc.
2600 N. W. Lake Road
CAMAS WA 98607-8542

Re: K063579
Trade/Device Name: Medical Display, MDC2130-2HC
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 13, 2006
Received: November 30, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Medical Display, MDC2130-2HC

Indications For Use: 2MP Medical Color Reference Display, MDC2130-2HC is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063579